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ORDER FOR SUPPLIES OR SERVICES SCHEDULE - CONTINUATION

PAGE NO

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 IMPORTANT: Mark all packages and papers with contract and/or order numbers.

 DATE OF ORDER
 CONTRACT NO.
 ORDER NO.

 07/23/2020
 HHSO100201200002I
 75A50120F33002

07/23/20	20 HHS0100201200002I			75A	50120F33002	
ITEM NO.	SUPPLIES/SERVICES	QUANTITY		UNIT	AMOUNT	QUANTITY
(a)	(b)	ORDERED (c)	(d)	PRICE (e)	(f)	ACCEPTED (g)
	See attached. Appr. Yr.: 2020 CAN: 199C014 Object Class: 25103 Period of Performance: 07/23/2020 to 12/31/2021					
	Operation Warp Speed CIADM Texas A&M University System (TAMUS) CIADM Manufacturing Capacity Reservation and Expansion				264,693,063.00	
	The total amount of award: \$264,693,063.00. The obligation for this award is shown in box 17(i).					
	Contractor to sign below: Som Mosford PhD Vice Chancellow for Research Texas Aim University System 7/24/20					
	TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))				\$264,693,063.00	AL FORM 348 (Per 4000

Contract Number: HHSO100201200002I Task Order Number: 75A50120F33002

B. COST / PRICE SCHEDULE

B.1 Prices

- **B.1.1** The total fixed price of this task order (sum of Task 1 and Task 2) is \$264,693,063.
- **B.1.2** The total fixed price of Task 1: Capacity Reservation is (b) (4)
- **B.1.3** The total fixed price of Task 2: Pharmaceutical Manufacturing Capacity Expansion is (b) (4)

B.2 Task 1 Payment Schedule

Following delivery and acceptance of the work described in **SECTION C.3.1 Task 1**: **Capacity Reservation** and the deliverables described in **SECTION F**, and on submission of an invoice in accordance with Section G.4 of this task order, the Government will pay the Contractor as follows (the "Reservation Fee"):

Item Description	Reporting Period	Due Date	Unit Price	Invoice Date
Provisional Construction Schedule for Task 2, Updated Equipment Procurement Dashboard, Official letter to BARDA reserving FBF areas HTP-1, HTP-2,and CC-3 through December 31, 2021	N/A	07/28/2020	(b) (4)	Upon Submittal
Monthly report #1	N/A	08/15/2020	(b) (4)	Upon Submittal
Monthly report #2	N/A	09/15/2020	(b) (4)	Upon Submittal
Manufacturing Schedule with Allocated Capacity through Period of Performance, as known #3	Oct-20	09/15/2020	(b) (4)	10/01/2020
Manufacturing Schedule with Allocated Capacity through Period of Performance, as known #4	Nov-20	10/15/2020	(b) (4)	11/01/2020

Manufacturing Schedule with Allocated Capacity through Period of Performance, as known #5	Dec-20	11/15/2020	(b) (4)	12/01/2020
Manufacturing Schedule with Allocated Capacity through Period of Performance, as known #6	Jan-21	12/15/2020	(b) (4)	01/01/2021
Manufacturing Schedule with Allocated Capacity through Period of Performance, as known #7	Feb-21	01/15/2021	(b) (4)	02/01/2021
Manufacturing Schedule with Allocated Capacity through Period of Performance, as known #8	Mar-21	02/15/2021	(b) (4)	03/01/2021
Manufacturing Schedule with Allocated Capacity through Period of Performance, as known #9	Apr-21	03/15/2021	(b) (4)	04/01/2021
Manufacturing Schedule with Allocated Capacity through Period of Performance, as known #10	May-21	04/15/2021	(b) (4)	05/01/2021
Manufacturing Schedule with Allocated Capacity through Period of Performance, as known #11	Jun-21	05/15/2021	(b) (4)	06/01/2021
Manufacturing Schedule with Allocated Capacity through Period of	Jul-21	06/15/2021	(b) (4)	07/01/2021

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Performance, as				
known #12				
Manufacturing	Aug-21	07/15/2021	(b) (4)	08/01/2021
Schedule with				
Allocated Capacity				
through Period of				
Performance, as				
known #13				
Manufacturing	Sep-21	08/15/2021	(b) (4)	09/01/2021
Schedule with				
Allocated Capacity				
through Period of				
Performance, as				
known #14				
Manufacturing	Oct-21	09/15/2021	(b) (4)	10/01/2021
Schedule with				
Allocated Capacity				
through Period of				
Performance, as				
known #15				
Manufacturing	Nov-21	10/15/2021	(b) (4)	11/01/2021
Schedule with				
Allocated Capacity				
through Period of				
Performance, as				
known #16				
Manufacturing	Dec-21	11/15/2021	(b) (4)	12/01/2021
Schedule with				
Allocated Capacity				
through Period of				
Performance, as				
known #17				
		Total =		

B.3 Task 2 Payment Schedule

Following delivery and acceptance of the work described in **SECTION C.3.2 Task 2: Pharmaceutical Manufacturing Capacity Expansion** and the delivery and acceptance of the deliverables described in **SECTION F**, and on submission of an invoice in accordance with Section G.4 of this task order, the Government will pay the Contractor as follows:

Milestone Description	Unit Price
Delivery of IMS, WBS, VPP Deliverables	
Completion of CQV Activities and Delivery of Validation Report	
for HTP-1 and HTP-2 to Enable Start of Engineering Run	

Contract Number: HHSO100201200002I Task Order Number: 75A50120F33002

Delivery of Validation Final Close-out Report to Enable GMP Runs	
Total =	

BARDA, TAMUS, and FDBT shall agree upon a "Manufacturing Schedule with Allocated Capacity" (Manufacturing Schedule) template and content during the initial program Kick Off meeting. FDBT shall use this template for the Manufacturing Schedule submittals. "Acceptable Manufacturing Schedules" shall be defined as containing content described in Section F.2.2. "Unacceptable Manufacturing Schedules" shall be defined as not containing all the content described in Section F.2.2.

BARDA, TAMUS, and FDBT shall agree upon a Monthly Report template and content during the initial program Kick Off meeting. FDBT shall use this template for the Monthly reports. "Acceptable Reports" shall be defined as containing content described in Section F.2.6. "Unacceptable Reports" shall be defined as not containing all the content described in Section F.2.6.

Any acceptance by the Government required under this Task Order shall not be unreasonably withheld or delayed. If the CO/COR reasonably determines that the Deliverable is an Unacceptable Report or an Unacceptable Manufacturing Schedule, it shall be returned to TAMUS within three (3) business days of submission of the deliverable with details of the specific deficiencies of the Deliverable. Any Contractor submitted deliverables not returned within three (3) business days of submission shall be deemed accepted by the Government.

TAMUS will invoice under NET 15 payment terms.

C. STATEMENT OF OBJECTIVES

C.1 Project Background

The Office of Assistant Secretary for Preparedness and Response (ASPR) was created within the Department of Health and Human Services (HHS) to lead the US in preventing, preparing for, and responding to the adverse health effects of public health emergencies and disasters. The Biomedical Advanced Research and Development Authority (BARDA), within ASPR, focuses on preparedness planning and response, building federal emergency medical operational capabilities and countermeasures research and advance development.

BARDA established a Center for Innovation in Advanced Development and Manufacturing (CIADM) with the Texas A&M University System (TAMUS), as a public-private partnership to ensure domestic vaccine manufacturing surge capacity to address national preparedness and response priorities. BARDA requires the services of the CIADM partners to provide core advanced development and manufacturing services ("industrialization") to other commercial partners under contract to the U.S. Government including HHS, ASPR, and BARDA ("the Government" or USG) for

Contract Number: HHSO100201200002I Task Order Number: 75A50120F33002

development of biopharmaceuticals against public health threats. Additionally, BARDA requires the CIADM partners to provide manufacturing facilities utilizing flexible manufacturing and advanced platform technologies to produce vaccines and other biopharmaceuticals for outbreaks of emerging infectious pathogens.

In December 2019, a novel (new) coronavirus known as SARS-CoV-2 ("the virus") was first detected in Wuhan, Hubei Province, People's Republic of China, causing outbreaks of the coronavirus disease COVID-19 that has now spread globally. The Secretary of Health and Human Services (HHS) declared a public health emergency on January 31, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID-19. On March 1, 2020, the President of the United States, pursuant to sections 01 and 301 of the National Emergencies Act (50 U.S.C. 1601 et seq.) and consistent with section 1135 of the Social Security Act (SSA), as amended (42 U.S.C. 1320b-5), proclaimed that the COVID-19 outbreak in the United States constitutes a national emergency.

Under the President's Operation Warp Speed Mission (OWS), the USG is leading a whole of nation effort with the primary goal to execute on a well-defined portfolio of COVID-19 vaccine candidates to maximize probability of having one or more safe and effective vaccines as fast as possible for mass distribution. As such, it is a national security concern to quickly make available safe and effective COVID-19 vaccines. One of several vaccine types being pursued by OWS are two vaccines that are produced in Sf9 cells. Sf9 cells are an insect cell line that can be used for expression of recombinant proteins and for propagation of baculovirus stocks to produce vaccines. To this end, the Government is seeking to reserve existing manufacturing capacity and expand manufacturing capacity in order to establish adequate domestic capabilities for the production of vaccines that use Sf9 cells in the manufacturing process. However, the facilities should be capable of producing any biological drug substance ("Drug Substance").

C.2 Objectives

The objective of this task order is to expand the public-private partnership with TAMUS to reserve and expand the capacities and capabilities established under the CIADM contract. The reserved capacity must include the facilities and equipment that have been renovated/constructed/purchased as well as services supported through the CIADM contract. The reservation must exclude the performance of any non-HHS/BARDA work in the reserved capacity without explicit, written approval from the BARDA Contracting Officer during the period of performance. The reserved manufacturing capacity must be capable of producing vaccines that use Sf9 cells in the manufacturing process. Any expansion efforts must further the ability to manufacture vaccines using Sf9 cells and/or any Drug Substance agreed to between FDBT and the Drug Substance Contractor (as defined below) and approved by HHS/BARDA.

C.3 Statement of Work: Tasks 1 and 2

Contract Number: HHSO1002012000021 Task Order Number: 75A50120F33002

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the tasks described below and on Attachment 1 to a level of sufficiency to ensure success of the intended utility.

C.3.1 Task 1: Capacity Reservation

The Contractor, in partnership with FUJIFILM Diosynth Biotechnologies, 3939 Biomedical Way, College Station, TX 77845 ("FDBT" or "Subcontractor"), will reserve current and newly created capacity within the Flexible Manufacturing Facility (FBF) building. Specifically, the Subcontractor will reserve FBF building capacity for BARDA around two of Subcontractor's existing Customers A and B ("Third Party Customers"). Current and new capacity will include areas of the FBF coming online through FDBT's previously planned investment which will be accelerated and enhanced under this Task Order (TO) to establish two (2) high throughput (HTP) areas in the FBF. Subcontractor will delay/cancel other existing third party customer commitments scheduled for production in the FBF during the period of performance. The delayed Third Party Customer programs will be transferred to The National Center for Therapeutics Manufacturing (NCTM) for production under this Task Order under the schedule in Table 1 below. Subject to signature of a subcontract between FDBT and TAMUS, BARDA will have the exclusive right to make the final determination and designation of the use of the capacity of the reserved FBF areas (HTP-1, HTP-2, and CC-3, as detailed below) to COVID-19 vaccine developers or other Drug Substance developers ("Drug Substance Contractor").

Subcontractor capacity availability activities include:

- Make current FBF suites available per the timeline in Table 1 which is based on an August 1, 2020 start date. Color code in Table 1 shall mean within the month indicated. Schedule is subject to risk from vendor supplied equipment and local COVID-19 case rates.
- Work diligently to establish the manufacturing capacity as rapidly as possible, including building in a rolling start up schedule (i.e. (b) (4)

). These approaches will be built into the validation and start up approach.

Contract Number: HHSO100201200002I Task Order Number: 75A50120F33002



Legend <u>Construction Status</u>
Ready for GMP Manufacturing Ready for Start up activities (equipment installation/validation and Tech Transfer) Existing Contracted Manufacturing

Table 1: FBF Suites available to HHS/BARDA

Contract Number: HHSO100201200002I Task Order Number: 75A50120F33002

The reservation of capacity is in the HTP-1, HTP-2, and CC-3 suites in the College Station facility of FDBT at address: FUJIFILM Diosynth Biotechnologies Texas, LLC, 3939 Biomedical Way,

College Station, TX 77845 (Figure 1 below):

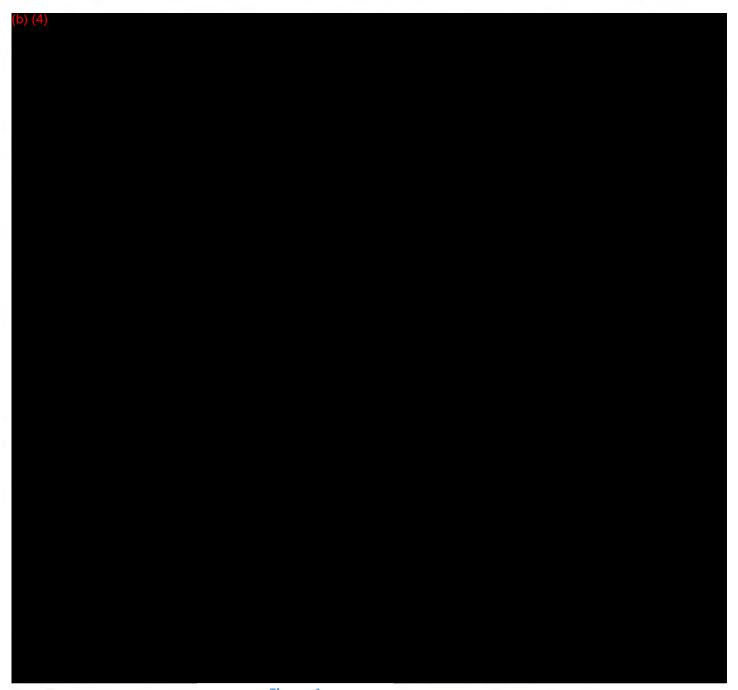


Figure 1

Contract Number: HHSO100201200002I Task Order Number: 75A50120F33002

- HTP-1, which includes Mobile Clean Rooms (MCRs) 1 and 2, will contain 4 x (b) (4) bioreactors each (b) (4) and associated equipment. The renovation of this suite will occur under Task 2.
- HTP-2, which includes two modular purification rooms, will contain 4 x (b) (4) bioreactors each (b) (4) and associated equipment. The renovation of this suite will occur under Task 2.
- CC-3 will be a convertible manufacturing suite to include a ninth (9th) (b) (4) bioreactor or two (2) (b) bioreactors and associated equipment based on the Drug Substance Contractor needs and approval of the Contracting Officer and Contracting Officer's Representative. Such requirements to be determined upon mutual signature of the Drug Substance Manufacturing Contract (as defined below) to allow time for, installation and qualification. If all of the bioreactors do not fit in the CC-3 facility, the equipment not used will be stored by FDBT for later use.

HTP 1 and 2 and CC-3 will have the capacity to perform (b) (4) volume manufacturing deploying single-use technology.

To accomplish these objectives, FDBT shall:

- Make current FBF suites available per schedule above (timeline is based on a program start date of 8/1/2020 but is subject to adjustment based on COVID-19 impact).
- Set up HTP areas with 4 x(b) (4) bioreactors (b) (4)
- Set up CC-3 area with either of the 1 x (b) (4) or 2 x (b) bioreactors based on the Drug Substance Contractor needs and approval by BARDA as detailed below in Task 2.
- Provide monthly report to include capacity availability, utilization, and risks (if any) to reserved capacity.
- Recruit, hire, and train 100 new staff members to support the requirements specified herein. Subcontractor must have achieved staffing levels of an additional 100 personnel with proper skill and required training to manufacture cGMP products in single use system vaccine technologies to staff HTP-1, HTP-2, and CC-3.
- Procure space to train and seat new staff members.

Subcontractor activities to support Subcontractor Third Party Customer program delays include:

 Delay/cancel or transfer to the NCTM the existing third party customer program contracts scheduled to be performed at FBF, and forego signing any new work with new or existing customers for services to be performed at the FBF during the period of performance.

Contract Number: HHSO1002012000021 Task Order Number: 75A50120F33002

- Purchase and install new four (4) new MCRs at NCTM. Pursuant to FAR 52.245-1, once Task 2 is complete as defined below, all ownership of Contractor Acquired Government Property under this task order shall transfer to the Subcontractor.
- Reconcile and final disposition of previous CIADM/BARDA equipment located at NCTM to make room for new MCRs at NCTM. BARDA will provide direction to TAMUS as to such disposition within fifteen (15) business days from the receipt of a complete list with appropriate detail of government furnished equipment residing in the NCTM in order to maintain agreed-to schedule.
- Procure, install, and validate new equipment at NCTM to support the third party customer programs transferred from FBF.

The Contractor and Subcontractor shall maintain the reserved capacities in a state of readiness to perform current good manufacturing practices (cGMP) manufacturing activities, approved by the USG during the period of performance.

On a monthly basis, the Contractor and FDBT shall provide a monthly report that includes capacity availability and utilization or non-utilization, as well as any issues that impact the operational availability of the reserved capacity. Additional details related to the Reserved Capacity may be required as frequently as daily.

C.3.2 Task 2: Pharmaceutical Manufacturing Capacity Expansion

Contractor and Subcontractor will expand current manufacturing capabilities, proposed at adding eight (8) (b) (4) bioreactors and associated equipment.

Additionally, a ninth (9th) (b) (4) bioreactor (currently owned by Subcontractor) or two (2) (b) bioreactors is included in this SOW and will be incorporated into the facilities based on the Drug Substance Contractor needs and approval of the Contracting Officer and Contracting Officer's Representative. Such requirements to be determined upon signature of Drug Substance Manufacturing Contract to allow time for installation and qualification.

Contractor will procure, install and validate all new equipment.

Contractor and Subcontractor will accelerate the existing FBF Building Expansion construction schedule around the existing Subcontractor Third Party Customers and expand current manufacturing capabilities.

Subcontractor facility expansion activities include:

 Accelerate necessary demolition and construction of the current facility plan.

- Acceleration of renovation and set up HTP-1 and HTP-2 areas with 2 x (4 x (b) (4)) bioreactors (b) (4)
- Accelerate the set-up of the CC-3 area with 1 x (b) (4) or 2 x b)
 bioreactors based on the Drug Substance Contractor needs subject to
 Subcontractor receiving notice upon signature of Drug Substance
 Manufacturing Contract to allow time for installation and qualification.
- Acceleration of procurement, installation, and validation of new and existing equipment.
- Identify and lease additional warehouse space.

The new capacity must be in compliance with FDA current good manufacturing practices (cGMP) regulations (21 CFR parts 210 and 211). The Contractor and FDBT shall be responsible for management of all activities, subcontractors, etc. to meet the goals of the Task Order, including holding routine meetings with BARDA, and completion of meeting minutes.

Pursuant to FAR 52.245-1, once Task 2 is complete as defined below, all ownership of Contractor Acquired Government Property under this task order shall transfer to the Subcontractor. In consideration for the Government's funding for this capacity expansion, the Contractor and FDBT agree to provide the Government priority access to the equipment funded by the government to the extent set forth in the current CIADM contract upon reasonable advance notice and subject to payment of reasonable fees. Until the end of useful life of the equipment at FDBT, the Subcontractor also agrees to fund any/all sustainment costs associated with maintaining the equipment/infrastructure procured by the Subcontractor and paid for by the Government pursuant to the Task Order. This maintenance includes compliance with FDA current good manufacturing practices (cGMP) regulations (21 CFR parts 210 and 211).

"Complete" means undertaking a complete CQV process to ensure appropriate installation, operation, and safe function of the systems installed (as applicable per Subcontractor validation policy). This includes IQ, OQ, and commissioning of HTP-1, HTP-2 and CC-3 to include all equipment required for start of engineering batches in a product agnostic manner. The rooms and equipment will be capable of manufacturing cGMP product. A detailed Validation Project Plan (VPP) described in Section F.2.5 shall be provided by Contractor. After performance of the test protocols and other items in the approved VPP, a Validation Close-Out report, which confirms all items identified in the VPP to be approved and closed out with all official documentation and signatures shall be provided as described in Section F.2.5.

On a monthly basis, the Contractor shall provide a monthly report that includes progress in establishing the expanded drug substance capacities including updates to the IMS. Additionally, the Contractor and FDBT may be called upon

Contract Number: HHSO100201200002I Task Order Number: 75A50120F33002

to provide in-depth details of progress on Task 2 Completion outside of the monthly report. Details may be required as frequently as daily.

(b) (4)

Α

summary report will be provided prior to entering into GMP operation for each area. Any PQ activities shall be covered under the Drug Substance Manufacturing Contracts.

D. PACKAGING AND MARKING

All deliverables required under this task order shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract and task order number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

E. INSPECTION AND ACCEPTANCE

Inspection and acceptance of all work, performance, reports and other deliverables, under this task order, will be performed at the CIADM's facility or approved subcontractor facility, by the Contracting Officer or the duly authorized representative of the Government.

The Contracting Officer's Representative (COR) is a duly authorized representative of the Government and is responsible for the inspection and acceptance of all items/activities to be delivered and or completed under this task order.

F. PERFORMANCE / DELIVERABLES

F.1 Period of Performance

The period of performance of this task order shall be from July 23, 2020 through December 31, 2021.

F.2 Deliverable Requirements

F.2.1 Report on NCTM Equipment Purchase, Personnel Acceleration, and Client Transfer Activities

This report shall include the planned equipment purchases and timeline for delivery, activities associated with accelerating the onboarding of additional personnel to support manufacturing activities, and the plan to transfer third party clients from the FBF to the NCTM.

F.2.2 Manufacturing Schedule with Allocated Capacity through Period of Performance

A prospective Manufacturing Schedule shall be provided monthly that includes the planned utilization and non-utilization of the reserved manufacturing capacities for the remaining period of performance. The schedule shall include:

Contract Number: HHSO1002012000021 Task Order Number: 75A50120F33002

- Length of time for manufacturing in each area
- Name of the teaming partner (i.e. Janssen, AstraZeneca, etc)
- Name of Vaccine
- Batch Size or Scale
- Number of batches

F.2.3 Integrated Master Schedule (IMS)

The IMS shall include the time-phased activities to completely execute the CWBS. A Microsoft Project compatible file is required and will result in a Gantt Chart for project tracking. The IMS will document the delivery date for each deliverable, critical path, major milestones, tasks/activities, duration, lead/lag/slack time, and schedule relationships, and will be directly traceable to the SOW and the WBS. The overall IMS will be developed to a level four (4), meaning a critical path has traceability. The IMS will contain details directly traceable to the SOW and the WBS to a minimum of a level five (5), meaning daily utilization of resources are identified for each task, for activities to be conducted within the following month. The IMS will be updated at least monthly, however, interim updates may be required but not more than every two weeks.

F.2.4 Work Breakdown Structure (WBS)

The WBS shall extend to elements to completely define the entire effort proposed to establish the capacity reservation and facility expansion as described in the SOW. The subcontractor will compose a WBS down to the work package level in accordance with the 100% rule as outlined in the PMBOK, 6th edition.

F.2.5 Validation Project Plan (VPP)

The VPP or set of VPP's shall define the activities, deliverables, responsibilities, and timeline associated with the validation of the facilities, utilities and equipment in the task order. Subcontractor shall provide copies of the VPP's and list of SOPs to Contractor who will forward to the CO/COR.

After performance of the test protocols and other items in the approved VPP, a Validation Close-Out report, which confirms all items identified in the VPP to be approved and closed out with all official documentation and signatures, shall be provided. Process Validation is excluded from this activity.

F.2.6 Monthly Report

In each monthly report the Contractor must include a description of the activities performed during the reporting period. Specific to Task 1, each monthly report must include a summary of capacity availability and utilization /

Contract Number: HHSO100201200002I Task Order Number: 75A50120F33002

non-utilization, as well as any issues that impact the operational availability of the reserved capacity. Specific to Task 2, each monthly report must include a summary of the progress in establishing the expanded drug substance manufacturing capacities, including updates to IMS. The actual content and format of the Monthly Report shall be agreed to at the Task Order Kick-Off Meeting as detailed in F.4.5.

F.3 Schedule of Deliverables

			Delivery	
Item	Task	Deliverable	Method	Due Date
1	1	Report on NCTM Equipment Purchase, Personnel Acceleration, and Client Transfer Activities	Electronically to CO and COR	Weekly, throughout period of performance until complete
2	1	Manufacturing Schedule with Allocated Capacity through Period of Performance, as known	Electronically to CO and COR	15 th day of every month throughout the task order period of performance
3	2	Integrated Master Schedule	Electronically to CO and COR	15 days after Task Order Award
4	2	Work Breakdown Structure	Electronically to CO and COR	15 days after Task Order Award
5	2	Validation Project Plan	Electronically to CO and COR	30 days after Task Order Award, implementation progress updates shall be provided in detail in the Monthly Reports and upon request.
6	2	Validation Close-Out report	Electronically to CO and COR	60 days after receipt of last piece of equipment from the vendor.

Contract Number: HHSO1002012000021 Task Order Number: 75A50120F33002

7	1 & 2	Monthly Report	Electronically to CO and COR	15 th day of every month throughout the task order period of
				performance

F.4 Meeting Requirements

F.4.1 Routine Update Teleconferences

The Contractor shall participate in regular teleconferences with USG to discuss the performance of the task order. The frequency will be agreed upon by the Contractor and USG and may be dependent on the activities during that time of the task order. Typically, these meetings are held bi-weekly or monthly. The Contractor is responsible for securing a suitable call in number for relevant participants and be responsible for moderating the meeting. The Contractor shall keep meeting minutes and forward a finalized copy to the CO and COR for approval within three (3) business days after each teleconference, or as otherwise authorized by the Contracting Officer.

F.4.2 Person-in-Plant

Requests for Person-in-Plant must be made to the Contractor at least two (2) weeks ahead of the date of the visit. The Contractor shall accommodate up to two (2) BARDA personnel at an agreed upon time throughout the performance of this task order subject to Subcontractor's Person-in-Plant SOP and internal policies. On-site BARDA personnel will provide support of the work and technical consultation in alignment with Contractor and per guidance from the BARDA program office in Washington, D.C. All visitors shall adhere to Subcontractor visitor guidelines and policies—particularly those related to COVID-19 safety.

F.4.3 Periodic Site Visits

The Contractor shall accommodate for periodic site visits by BARDA on an ad hoc basis or as agreed upon, with at least two (2) weeks' prior written notice to the Contractor. The Subcontractor shall accommodate up to a total of five (5) visitors during such visits. The Contractor shall keep meeting minutes and forward a finalized copy to the Contracting Officer and COR for approval within three (3) business days after each site visit, or as otherwise authorized by the CO. All visitors shall adhere to Subcontractor visitor guidelines and policies—particularly those related to COVID-19 safety.

F.4.4 Quarterly Site Visits

Contract Number: HHSO1002012000021 Task Order Number: 75A50120F33002

The Contractor shall provide formal presentations summarizing all work accomplished in the previous calendar quarter at the Contractor's site on a quarterly basis. The Contractor shall keep meeting minutes and forward a finalized copy to the CO and COR for approval within three (3) business days after each site visit, or as otherwise authorized by the CO.

F.4.5 Kick-Off Meeting

The Contractor shall participate in a kick-off meeting, within 14 days of task order award; content, format, and location to be determined by the USG and the Contractor. The Contractor is responsible for securing a physical location or a suitable call in number for relevant participants and be responsible for moderating the meeting. The Contractor shall keep meeting minutes and forward a finalized copy to the Contracting Officer and COR for approval within three (3) business days after the meeting is held, or as otherwise authorized by the Contracting Officer.

G. CONTRACT ADMINISTRATION

G.1 Contracting Officer

The following COs will represent the Government for the purpose of this task order:

Carol Lavrich, Carol.Lavrich@hhs.gov

The CO is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the CO can make any changes to the terms, conditions, general provisions, or other stipulations of this task order.

The CO is the only person with the authority to act as agent of the Government under this task order. Only the CO has authority to (1) direct or negotiate any changes in the Statement of Work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor of any costs incurred during the performance of this task order; and (5) otherwise change any terms and conditions of this task order; or (6) sign written licensing agreements.

No information other than that which may be contained in an authorized modification to this task order, duly issued by the CO, which may be received from any person employed by the Government, or otherwise, shall be considered grounds for deviation from any stipulation of this task order.

The Government may unilaterally change its CO designation, after which it will notify the Contractor in writing of such change.

G.2 Contracting Officer's Representative

The following Contracting Officer's Representative (COR) will represent the Government for the purpose of this task order:

Contract Number: HHSO1002012000021 Task Order Number: 75A50120F33002

Timothy Belski, *Timothy.Belski@hhs.gov*

The COR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the scope of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this task order. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this task order; (5) otherwise change any terms and conditions of this task order; or (6) sign written licensing agreements. If the Contractor believes that technical direction provided by the COR constitutes a change to the terms and conditions of this task order, the Contractor shall promptly notify the Contracting Officer in writing.

The Government may unilaterally change its COR designation.

G.3 Key Personnel

Key personnel specified in this task order are considered to be essential to work performance. At least 30 days prior to the Contractor voluntarily diverting any of the specified individuals to other programs or contracts, the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement, and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience and credentials meet or exceed the requirements of the task order (including, when applicable, Human Subjects Testing requirements). If the employee of the Contractor is terminated for cause or separates from the Contractor voluntarily with less than 30 day notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace or announce any such change to key personnel without the written consent of the Contracting Officer; provided that the Contracting Officer may ratify in writing that such diversion and such ratification shall constitute the consent of the Contracting Officer required by this clause. The task order will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

The following individuals are determined to be key personnel:

Name	Title
(b) (6)	Principle Investigator
(b) (6)	Executive Director
(b) (6)	Director of Contract Management

Contract Number: HHSO1002012000021 Task Order Number: 75A50120F33002

(b) (6) FDBT, Chief Business Officer	
(b) (6)	FDBT, Vice President of Engineering and
	Asset Development
(b) (6)	FDBT, Contracts Manager

G.4 Invoicing Instructions

Invoices for payment shall be submitted electronically and shall include an SF-1034 and all supporting documentation (such as copies of the reports or the deliverables described in Section F, as applicable), per any payment instructions provided in the base contract and the Contracting Officer. This supporting documentation shall be in lieu of any additional obligation to provide any supplemental backup information.

G.5 Evaluation of Contractor Performance

Purpose: In accordance with FAR 42.1502(a), past performance evaluations shall be prepared at least annually and at the time the work under a contract or order is completed, via CPARS, the Government-wide evaluation tool (www.cpars.gov).

Evaluators: The performance evaluation will be completed jointly by the Contracting Officer's Representative and the Contracting Officer.

Performance Evaluation Factors: Per FAR 42.1503(b)(2), evaluation factors for each assessment shall include, at a minimum: technical (quality of product or service); cost control; schedule/timeliness; management and business relations; small business subcontracting; other (as applicable).

Contractor Review: A copy of the evaluation will be electronically sent to the Contractor as soon as practicable after completion of the evaluation. The Contractor shall submit comments, rebutting statements, or additional information to the Contracting Officer within 14 calendar days after receipt of the evaluation.

Resolving Disagreements between the Government and the Contractor: Disagreements between the parties regarding the evaluation will be reviewed at a level above the Contracting Officer. The ultimate conclusion on the performance evaluation is a decision of the contracting agency. Copies of the evaluation, Contractor's response, and review comments, if any, will be retained as part of the evaluation.

Release of Contractor Performance Evaluation Information: The completed evaluation will not be released to other than Government personnel and the Contractor whose performance is being evaluated. Disclosure of such information could cause harm both to the commercial interest of the Government and to the competitive position of the Contractor being evaluated, as well as impede the efficiency of Government operations.

Source Selection Information: Departments and agencies may share past performance information with other Government departments and agencies when requested to

Contract Number: HHSO1002012000021 Task Order Number: 75A50120F33002

support future award decisions. The information may be provided through interview and/or by sending the evaluation and comment document to the requesting source selection official.

Retention Period: The agency will retain past performance information for a maximum period of 3 years after completion of task order performance for the purpose of providing source selection information for future contract awards.

H. SPECIAL REQUIREMENTS

H.1 Advance Understandings

- H.1.1 The Government recognizes that Contractor and FDBT's operations are essential as a matter of national security and, as such, Contractor and FDBT are directed to maintain operations to the extent practicable regardless of state or local restrictions to the contrary. In addition, all Contractor and FDBT employees, independent contractors, and subcontractors are considered essential personnel supporting critical infrastructure as set forth in DHS CISA Memorandum dated March 19, 2020.
- H.1.2 The Government confirms that all activities conducted by Contractor, FDBT, any independent contractors and subcontractors under this task order as well as all general operations necessary to ensure execution of activities under this task order are subject to certain declarations under the Public Readiness and Emergency Preparedness Act (PREP Act) issued by the Secretary of Health and Human Services on March 10, 2020.
- H.1.3 The Government reserves the right to exercise priorities and allocations authority with respect to this task order, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System. Contractor and FDBT agrees that the Government's right to exercise priorities and allocations authority with respect to this order, to include the use of directives in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System, constitutes a no-cost change to this order. The Contracting Officer may unilaterally modify the task order to assign a Health and Human Services priority rating under Defense Priorities and Systems Regulation (15 CFR 700).
- H.1.4 FDBT will act as the Contract Development Manufacturing Organization (CDMO) for priority targets as determined by the Government and the scope will encompass Drug Substance. The reserved capacity will be utilized for manufacturing cGMP Drug Substance on behalf of the Government, which is currently planned to occur under a separate US Government contract ("Drug Substance Manufacturing Contract") with a Drug Substance Contractor, which will engage FDBT as a subcontractor.

Contract Number: HHSO100201200002I Task Order Number: 75A50120F33002

> H.1.5 Upon approval of a direct relationship between FDBT and the Drug Substance Contractor, the Government will release the associated capacity to Contractor and FDBT for FDBT to deploy and contract with the identified Drug Substance Contractor by the Government.

The reserved capacity under this task order shall be utilized for manufacturing cGMP Drug Substances on behalf of the Government under the Drug Substance Manufacturing Contract. FDBT will negotiate pricing with the identified Drug Substance Contractor for producing cGMP Drug Substance including manufacturing batch fees and raw materials. Manufacturing batch fees shall be inclusive of all FDBT's costs necessary to manufacture a batch of Drug Substance

negotiated under the Drug Substance Manufacturing Contract ("Manufacturing Batch Fees"). Reservation Fees paid by BARDA under this task order will be credited to any and all of the Manufacturing Batch Fees negotiated under the Drug Substance Manufacturing Contract for work related to producing the cGMP Drug Substance.

FDBT will credit any and all uncredited Reservation Fees paid by BARDA under Task 1 at the rate of (b) (4) per manufacturing batch. The balance of the Manufacturing Batch Fee will be paid through the Drug Substance Manufacturing Contract.

- H.1.6 FDBT will receive 100% of each monthly Reservation Fee payment as long as this task order is active and within its period of performance, regardless of the number of Drug Substance Manufacturing Contract batch runs actually contracted for during any given month during the performance period of the Drug Substance Manufacturing Contract. FDBT will credit all of the Reservation Fees paid by HHS/BARDA under Task 1 of this task order to any and all Drug Substance batch runs actually performed by FDBT in accordance with the price application described in the preceding paragraphs.
- **H.1.7** FDBT shall provide complete transparency as to how the Reservation Fee credits are being applied to the manufacturing of the drug substance batches. HHS/BARDA shall have the right to perform audits as it deems necessary.
- **H.1.8** TAMUS shall ensure that (b) (4) of the fee provided to it under this task order are used to directly support the CIADM program and its mission of pandemic preparedness. The scope of these initiatives include, but are not limited to:
 - CIADM operational costs
 - CIADM equipment maintenance
 - CIADM equipment replacement
 - CIADM workforce certification and training
 - Research initiatives that support the CIADM mission

Contract Number: HHSO1002012000021 Task Order Number: 75A50120F33002

Recruitment incentives beyond what TAMUS may offer for CIADM employees

Future CIADM capability expansions and operations

H.2 Intellectual Property

The parties do not anticipate the development of any intellectual property under this task order. However, to the extent intellectual property is developed, FAR 52.227-11 and FAR 52.227-14 shall apply.

H.3 Non-Personal Services and Inherently Governmental Functions

Pursuant to FAR 37.1, no personal services shall be performed under this contract. All work requirements shall flow only from the Contracting Officer's Representative (COR) and/or the Contracting Officer to the Contractor's Project Manager. No Contractor or FDBT employee will be directly supervised by the Government. All individual employee assignments, and daily work direction, shall be given by the applicable employee supervisor. If the Contractor believes any Government action or communication has been given that would create a personal services relationship between the Government and any Contractor employee, the Contractor shall promptly notify the Contracting Officer of this communication or action.

Pursuant to FAR 7.5, the Contractor or FDBT shall not perform any inherently Governmental actions under this task order. No Contractor employee shall hold him or herself out to be a Government employee, agent, or representative. No Contractor employee shall state orally or in writing at any time that he or she is acting on behalf of the Government. In all communications with third parties in connection with this task order, Contractor employees shall identify themselves as Contractor employees and specify the name of the company for which they work. In all communications with other Government contractors in connection with this task order, the Contractor employee shall state that they have no authority to in any way change the task order and that if the other contractor believes this communication to be a direction to change their task order, they should notify the Contracting Officer for that task order and not carry out the direction until a clarification has been issued by the Contracting Officer.

The Contractor shall ensure that all of their employees working on this task order are informed of the substance of this article. Nothing in this article shall limit the Government's rights in any way under the other provisions of the task order, including those related to the Government's right to inspect and accept the services to be performed under this task order. The substance of this article shall be included in all subcontracts at any tier.

H.4 Organizational Conflict of Interest

H.4.1 General: For the purpose of this provision/clause, "consultant" is defined as a company, firm, LLC, sole proprietor, joint venture member, independent

Contract Number: HHSO1002012000021 Task Order Number: 75A50120F33002

contractor, subcontractor, affiliate, or similar entity that is not an employee of the Contractor.

- H.4.2 Disclosure: The Contractor shall report contacts with consultants who are paid to furnish advice, information, direction, or assistance to the Contractor or FDBT or any subcontractor in support of the preparation or submission of the Contractor or FDBT's business or technical proposal. The report shall include the following information:
 - (i) The name, title, and contact information for the consultant, including the name and contact information for his/her company/firm/etc.
 - (ii) The name, title, and contact information for a Contractor or FDBT point of contact, including the name and contact information for the prime contractor if the consulting services were received by a subcontractor.
 - (iii) The nature of the consulting services received.
- H.4.3 Resolution: The responsible Contracting Officer will review the Contractor and/or FDBT and/or any relevant party's disclosure to determine whether an actual or appearance of a conflict of interest exists based on the information disclosed by the Contractor and/or from other sources. The framework for the Contracting Officer's review will be FAR Subpart 9.5, Organizational and Consultant Conflicts of Interest. If an actual or appearance of a conflict of interest exists, the Contracting Officer will take action which may include, but is not limited to, requesting a mitigation plan from the Contractor.
- **H.4.4** All above requirements must be passed to all Sub-contractors.

I. CONTRACT CLAUSES

I.1 FAR 52.252-2 Clauses Incorporated by Reference (Feb 1998)

This task order incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: https://www.acquisition.gov/.

I.2 FAR Clauses Incorporated by Reference

All clauses incorporated in the base contract including any Clauses Applicable to Design and Construction (Base Period) are in full effect at the task order level.

The following clauses are also incorporated by reference:

Clause No.	Date	Clause
52.236-2	Apr 1984	Differing Site Conditions.
52.236-3	Apr 1984	Site Investigation and Conditions Affecting the Work.

Contract Number: HHSO100201200002I Task Order Number: 75A50120F33002

52.236-5	Apr 1984	Material and Workmanship.
52.236-6	Apr 1984	Superintendence by the Contractor.
52.236-7	Nov 1991	Permits and Responsibility.
52.236-8	Apr 1984	Other Contracts.
52.236-9	Apr 1984	Protection of Existing Vegetation, Structures, Equipment,
		Utilities, and Improvements.
52.236-10	Apr 1984	Operations and Storage Areas.
52.236-11	Apr 1984	Use and Possession Prior to Completion.
52.236-12	Apr 1984	Cleaning Up.
52.236-13	Nov 1991	Accident Prevention.
52.236-14	Apr 1984	Availability and Use of Utility Services.
52.236-21	Feb 1997	Specifications and Drawings for Construction.

I.3 Additional FAR Contract Clauses Included in Full Text

This task order incorporates the following clauses in full text:

I.3.1 FAR Clause 52.236-1 Performance of Work by the Contractor (Apr 1984)

The Contractor shall perform on the site, and with its own organization, work equivalent to at least zero (0) percent of the total amount of work to be performed under the contract. This percentage may be reduced by a supplemental agreement to this contract if, during performing the work, the Contractor requests a reduction and the Contracting Officer determines that the reduction would be to the advantage of the Government.

(End of clause)

J. ATTACHMENTS

The following documents are attached and incorporated in this contract:

Attachment 1 – Task and Task 2 Work Items and Equipment Lists

Attachment 2 – Contractor-Subcontractor Payment Schedule

Attachment 1 is attached to this document and incorporated by reference.

K. REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS

The Representations and Certifications required by and included in the base contract are in full effect at the task order level.

Attachment 1 – Task 1 and Task 2 Work Items and Equipment Lists

CIADM Manufacturing Capacity Reservation and Expansion

Task 1 includes:

WBS 01 Capacity Reservation

- Facility value during initial 3 month period (1/2 value of full scale utilization) less 3rd party utilization
- Facility value at full utilization per month (based on (b) (4) at an estimated price of (b) (4)

WBS 02 Personnel Acceleration which includes, but is not limited to:

- Recruiters
- Relocations
- Training and training space

WBS 03 Client Transfer to NCTM which includes, but is not limited to:

- Document updates
- Move/install/requalification equipment estimate

WBS 04 NCTM Fit Up which includes, but is not limited to:

Equipment Description	Qty
(b) (4) 25	2
50L BRX	2
200L BRX	1
(b) (4) 200L	2
(b) (4) 500L	4
(b) (4) 1000L	2
(b) (4)	1
Freezers	6
Filling Systems	2
Incubators	2
Harvest Skid - MVP controller	1
Harvest Skid - 3 Stack POD holder	1
(b) (4) Isolators	2
Mobile Clean Rooms (MCRs)	4
Infrastructure Upgrades (Automation/b) (4	4)
All equipment listed above plus existing eq	uipment hooked up to automation
system	
Software licenses, networking, validation of	f software
Onsite Validation of Equipment	

Construction and A/E: All Facility modifications to support additional MCRs, modified facility airlocks, electrical and gas service, waste line attachments.

Small equipment for analytics, in process testing, validation consumable costs

Task 2 includes:

WBS 05: Facility Capital Equipment which includes:

Equipment Description	Qty				
	CC3	HT-1	HT-2		
(b) (4) 25	1	2	2		
50L BRX	1	2	2		
200L BRX	0	1	1		
500L BRX	2	2	2		
2000L BRX	0	4	4		
(b) (4) 200L	2	2	3		
(b) (4) 500L	2	4	4		
(b) (4) 1000L	0	2	2		
(b) (4) 2500L	0	1	1		
(b) (4)	1	3	3		
(b) (4)	0	1	1		
Freezers	2	3	3		
Filling Systems	0	1	1		
Incubators	3	4	4		
Harvest Skid - (b) (4)	1	2	2		
Harvest Skid - (b) (4)	1	2	2		
TFF - (b) (4)	1	1	1		
(b) Centrifuge	0	3			
(b) (4) Isolators	1	1	1		
Infrastructure Upgrades (Automation(b) (4))				
All equipment listed above plus existing equi					
hooked up to automation system					
Software licenses, networking, validation of s	oftware				
Onsite Validation of Equipment					
Small equipment for analytics, in process tes	ting,				
validation consumable costs					

WBS 06: Capital Acceleration of Construction to cover all Facility modifications and includes but is not limited to the following items:

Construction Manager (b)		
Accelerated Field labor		
Accelerated Home office labor		
Reimbursable CM General conditions		

A	l		
ΔCCD	IERATION	of Demo	IITIAN

Acceleration of Building Shell

Acceleration of Interior Construction

Acceleration of MEP, Process Piping & Controls

Acceleration of procurement of Process Equipment

Contractual Allowances: Cover any unexpected costs associated with acceleration of existing facility infrastructure

Acceleration of Design

Construction Backup Allowances: Cover impacts to personnel, etc. caused by acceleration

Acceleration of CM activities

CG&L Insurance

Accelerated NCTM Labor

Labor Acceleration

Vendor Expediting to meet schedule

Labor Back up Allowances: Cover unexpected impacts to personnel etc., caused by acceleration

WBS 07: Warehouse Space Setup which includes, but is not limited to:

- Dock build estimate (demo work and dock equipment)
- Warehouse equipment set up/rack install estimate (pallet/fork trucks, racks, cold storage and cold storage monitoring)

Attachment 2 – Contractor-Subcontractor Payment Schedule

CIADM Manufacturing Capacity Reservation and Expansion

Task 1:

Item Description	Reporting Period	Due Date	TAMUS Price	FDBT Price	Total Price
Provisional Construction Schedule for Task 2, Updated Equipment Procurement Dashboard, Official letter to BARDA reserving FBF areas HTP-1, HTP-2,and CC-3 through December 31,	N/A	07/28/2020	(b) (4)		
2020 Monthly Report	N/A	08/15/2020	(b) (4)		
#1 Monthly Report #2	N/A	09/15/2020	(b) (4)		
Manufacturing Schedule with Allocated Capacity through Period of Performance, as known #3	Oct-20	09/15/2020	(b) (4)		
Manufacturing Schedule with Allocated Capacity through Period of Performance, as known #4	Nov-20	10/15/2020	(b) (4)		
Manufacturing Schedule with Allocated Capacity	Dec-20	11/15/2020	(b) (4)		

through Period				
of Performance,				
as known #5				
Manufacturing	Jan-21	12/15/2020	(b) (4)	
Schedule with				
Allocated				
Capacity				
through Period				
of Performance,				
as known #6				
Manufacturing	Feb-21	01/15/2021	(b) (4)	
Schedule with	10021	01/15/2021	(D) (4)	
Allocated				
Capacity				
through Period				
of Performance,				
as known #7				
	Mar-21	02/15/2021		
Manufacturing	Mar-21	02/15/2021	(b) (4)	
Schedule with				
Allocated				
Capacity				
through Period				
of Performance,				
as known #8				
Manufacturing	Apr-21	03/15/2021	(b) (4)	
Schedule with				
Allocated				
Capacity				
through Period				
of Performance,				
as known #9				
Manufacturing	May-21	04/15/2021	(b) (4)	
Manufacturing	Jun-21	05/15/2021	(b) (4)	
Schedule with				
Allocated				
Capacity				
through Period				
of Performance,				
as known #11				
Schedule with Allocated Capacity through Period of Performance, as known #10 Manufacturing Schedule with Allocated Capacity through Period	ŕ			

Manufacturing	Jul-21	06/15/2021	(b) (4)	
Schedule with				
Allocated				
Capacity				
through Period				
of Performance,				
as known #12				
Manufacturing	Aug-21	07/15/2021	(b) (4)	
Schedule with				
Allocated				
Capacity				
through Period				
of Performance,				
as known #13				
Manufacturing	Sep-21	08/15/2021	(b) (4)	
Schedule with	•	,		
Allocated				
Capacity				
through Period				
of Performance,				
as known #14				
Manufacturing	Oct-21	09/15/2021	(b) (4)	
Schedule with		, , ,		
Allocated				
Capacity				
through Period				
of Performance,				
as known #15				
Manufacturing	Nov-21	10/15/2021	(b) (4)	
Schedule with				
Allocated				
Capacity				
through Period				
of Performance,				
as known #16				
Manufacturing	Dec-21	11/15/2021	(b) (4)	
Schedule with	20021	11, 13, 2021	(D) (T)	
Allocated				
Capacity				
through Period				
of Performance,				
as known #17				
as KIIOWII #1/		Total =	(b) (4)	
		างเลา =	(b) (4)	

Attachment 2

Task 2:

Milestone Description	TAMUS Price	FDBT Price	Total Price
Delivery of IMS, WBS, VPP Deliverables	(b) (4)		
Completion of CQV Activities and Delivery of	(b) (4)		
Validation Report for HTP-1 and HTP-2 to			
Enable Start of Engineering Run			
Delivery of Validation Final Close-out Report	(b) (4)		
to Enable GMP Runs			
Total =	(b) (4)		(b) (4)